

Application No. 10/569,583

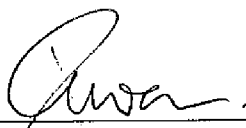
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/569,583	First Named Inventor: Neil Gallagher
371 Filing Date: February 23, 2006	Attorney Docket No.: 101213-1P US
Examiner: Julie Ha	Group Art Unit : 1654
Customer No.: 44992	Confirmation No.: 5947
Title: Combination comprising N-(3-methoxy-5-methylpyrazin-2-yl)-2-(4-[1,3,4-oxadiazol-2-yl]phenyl)pyridine-3-sulphonamide and an LHRH analogue and/or bisphosphonate	

Commissioner for Patents
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JON OWEN CURWEN'S STATEMENT UNDER 37 C.F.R. § 1.48(a)(2)

I, Jon Owen Curwen, am the person being added as an inventor to correct the inventorship of U.S. Patent Application No.10/569,583 and do hereby declare the error resulting in my being omitted as an inventor of U.S. Patent Application No.10/569,583 occurred without any deceptive intent on my part.



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Dated: 1st August 2008

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ZD4054 Update Analysis Results

Bisphosphonate usage

Bisphosphonate study restrictions

- **Bisphosphonate therapy:**
 - Patients taking bisphosphonates must be on stabilised dose for ≥ 6 wks prior to randomisation and remain on same dose. Bisphosphonate therapy, if infused, must be administered ≥ 1 wk before bone scans are performed.
 - In patients where bisphosphonates was stopped prior to study entry, there must be a washout of 4 wks prior to randomisation.
 - Patients not on bisphosphonate therapy at randomisation should not commence any bisphosphonate therapy whilst on study.

(as amended by Protocol Amendment 1, dated 21 March 2005)

Summary of Bisphosphonate usage

Treatment	ZD4054 15mg N=98	ZD4054 10mg N=107	Placebo N=107
Bisphosphonates	30 (30.6)	30 (28.0)	33 (30.8)
ALENDRONATE SODIUM	1 (1.0)	2 (1.9)	1 (0.9)
BONDRONAT	0 (0.0)	1 (0.9)	1 (0.9)
CLODRONATE DISODIUM	3 (3.1)	1 (0.9)	4 (3.7)
IBANDRONATE SODIUM	0 (0.0)	1 (0.9)	0 (0.0)
IBANDRONIC ACID	1 (1.0)	0 (0.0)	0 (0.0)
PAMIDRONATE DISODIUM	0 (0.0)	2 (1.9)	1 (0.9)
RISEDRONATE SODIUM	0 (0.0)	1 (0.9)	2 (1.9)
ZOLEDRONIC ACID	25 (25.5)	22 (20.6)	25 (23.4)

Progression Free Survival

(Full analysis set)

Base Model	HR (80%CI)	p-value
ZD4054 10mg vs. Placebo	1.09 (0.91,1.31)	0.553
ZD4054 15mg vs. Placebo	0.94 (0.78,1.14)	0.702
Bisphosphonate usage as covariate (exploratory)		
ZD4054 10mg vs. Placebo	1.10 (0.91,1.32)	0.523
ZD4054 15mg vs. Placebo	0.95 (0.78,1.15)	0.714

Overall Survival

(Full analysis set)

	HR (80%CI)	P-value
Base Model		
ZD4054 10mg vs. Placebo	0.55 (0.41,0.73)	0.008
ZD4054 15mg vs. Placebo	0.65 (0.49,0.86)	0.052
Bisphosphonate usage as covariate (exploratory)		
ZD4054 10mg vs. Placebo	0.55 (0.41,0.73)	0.008
ZD4054 15mg vs. Placebo	0.65 (0.49,0.86)	0.051